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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,808	09/16/2003	Sylvie Roux	03495.0174-02000	2497

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EXAMINER	
CHEN, SHIN LIN	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/662,808	ROUX ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-65 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-65 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, drawn to a method for *in vivo* delivery of a desired composition into human or animal CNS or spinal cord by using a **proteolytic fragment** of tetanus toxin (TT) in association with at least a molecule having a biological function, classified in class 514, subclass 4.

II. Claims 12-16 and 27-30, drawn to a method for *in vivo* delivery of a desired composition into human or animal CNS or spinal cord by using a **vector** containing nucleotide sequence encoding hybrid fragment of TT in association with at least a molecule having a biological function, classified in class 435, subclass 455.

III. Claims 17-19 and 21-23, drawn to a hybrid peptide fragment of tetanus toxin comprising a fragment C and a fragment B or a fraction thereof at least 11 amino acid residues, classified in class 530, subclass 300.

IV. Claims 20, 24 and 31, drawn to a polynucleotide variant fragment capable of hybridizing with a natural tetanus toxin sequence, and a vector or a cell containing a promoter and a nucleic acid coding for the fragment of TT, wherein said nucleic acid is associated with a polynucleotide coding for a protein, classified in classes 435 and 424, subclasses 320.1 and 93.2, respectively.

V. Claim 25, drawn to a method of treatment of a patient by delivering a composition comprising a **hybrid fragment of TT**, classified in class 514, subclass 4.

VI. Claim 26, drawn to a method of treatment of a patient by delivering a composition comprising **a vector** expressing hybrid fragment of TT, classified in class 514, subclass 44.

VII. Claims 27-30, drawn to a method for *in vivo* delivery of a desired composition into human or animal CNS or spinal cord by using **a cell** containing nucleotide sequence encoding hybrid fragment of TT in association with at least a molecule having a biological function, classified in class 424, subclass 93.2 and 93.21.

VIII. Claims 32-35, 37, 40, 41 and 43, drawn to a method of modulating the transport in neuron of a tetanus toxin or a fusion protein comprising a fragment C of the tetanus toxin by administering to the neuron a **TrkB receptor agonist**, which is a **neurotrophic factor**, classified in class 435, subclass 7.2.

IX. Claims 32, 33, 36 and 37, drawn to a method of modulating the transport in neuron of a tetanus toxin or a fusion protein comprising a fragment C of the tetanus toxin by administering to the neuron a **TrkB receptor agonist**, which is an **antibody**, classified in class 435, subclass 7.1.

X. Claims 32, 38, 39 and 42, drawn to a method of modulating the transport in neuron of a tetanus toxin or a fusion protein comprising a fragment C of the tetanus toxin by administering to the neuron a **TrkB receptor antagonist**, which is an **antibody**, classified in class 435, subclass 7.1.

XI. Claims 44-47, 49 and 52-55, drawn to a method of modulating the transport in neuron of a tetanus toxin or a fusion protein comprising a fragment C of the

tetanus toxin by administering to the neuron a **GFRalpha/cRET receptor agonist**, which is a **neurotrophic factor**, classified in class 435, subclass 7.2.

XII. Claims 44 and 48, drawn to a method of modulating the transport in neuron of a tetanus toxin or a fusion protein comprising a fragment C of the tetanus toxin by administering to the neuron a **GFRalpha/cRET receptor agonist**, which is an **antibody**, classified in class 435, subclass 7.1.

XIII. Claims 44, 50 and 51, drawn to a method of modulating the transport in neuron of a tetanus toxin or a fusion protein comprising a fragment C of the tetanus toxin by administering to the neuron a **GFRalpha/cRET receptor antagonist**, which is an **antibody**, classified in class 435, subclass 7.1.

XIV. Claims 56-58, drawn to a composition comprising a TrkB receptor agonist and a fusion protein comprising a fragment C of the tetanus toxin fused to a second protein, classified in class 435, subclass 69.7.

XV. Claims 59-61, drawn to a composition comprising a GFRalpha/cRET receptor agonist and a fusion protein comprising a fragment C of the tetanus toxin fused to a second protein, classified in class 435, subclass 69.7.

XVI. Claims 62-64, drawn to a method of detecting an effect of a compound or screening a compound on neuronal transport by administering to a neuron the compound and a fusion protein comprising a fragment C of the tetanus toxin fused to a second protein, and detecting the second protein to determine the effect of the compound on neuronal transport, classified in classes 435 and 436, subclasses 7.9 and 2, respectively.

Claims 27-30 link(s) inventions II and VII. Claim 32 link(s) inventions VIII-X. Claims 33 and 37 link(s) inventions VIII and IX. Claim 44 link(s) inventions XI-XIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 27-30. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also M.E.P.. § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Groups I, II and VII are distinct from each other because they are drawn to methods of using different compositions having different chemical structures, physical properties and biological functions, and requiring separate search: peptides, nucleic acids (vector), and cells. They are methods which differ at least in method steps, reagents and/or dosages used, schedules used, response variables, and criteria for success. They have different classifications and require separate search. Thus, they are patentably distinct from each other. Similarly, groups V and VI are patentably distinct from each other for the same reasons.

Groups III and IV are distinct from each other because they are drawn to compositions having different chemical structures, physical properties and biological functions, and requiring separate search: peptides vs. nucleic acids (vector) or cells. A search for peptides does not

require a search for nucleic acids or cells and vice versa. They have different classifications and the search would not be coextensive. Thus, they are patentably distinct from each other.

Groups I-II, VII are distinct from groups V-VI because they are drawn to methods that differ at least in objectives, method steps, reagents and/or dosages used, schedules used, response variables, and criteria for success. A method of treating a disease differs from a method of delivering to a subject. They have different classifications and require separate search. Thus, they are patentably distinct from each other.

Groups III-IV are distinct from groups I-II and V-VII. Group III-IV and groups I-II and V-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.E.P.. § 806.05(h)). In the instant case the hybrid peptide fragment of TT can be used to produce antibody and for purification of said antibody. The vectors or cells can be used for producing a recombinant protein or used as an antigen to stimulate immune response in an animal.

Groups VIII-X are distinct from each other because they are drawn to methods of using different compositions having different chemical structures, physical properties and biological functions, and requiring separate search: TrkB receptor **agonist** that is a neurotrophic factor, TrkB receptor **agonist** that is an antibody, and TrkB receptor **antagonist** that is an antibody. Agonist antibody is different from antagonist antibody. They are drawn to methods that differ at least in method steps, reagents and/or dosages used, schedules used, response variables, and criteria for success. They have different classifications and require separate search. Thus, they

are patentably distinct from each other. Similarly, groups XI-XIII are patentably distinct from each other for the same reasons.

Groups XIV and XV are distinct from each other because they are drawn to compositions having different chemical structures, physical properties and biological functions, and requiring separate search: TrkB receptor agonist vs. GFRalpha/cRET receptor agonist. A search for TrkB receptor agonist does not require a search for GFRalpha/cRET receptor agonist and vice versa. The search would not be coextensive. Thus, they are patentably distinct from each other. Groups XIV-XV are distinct from groups III-IV for the same reason.

Group XIV is patentably distinct from groups VIII-IX. Group XIV and groups VIII-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.E.P.. § 806.05(h)). In the instant case the fusion protein comprising a fragment C of TT can be used to produce antibody and for purification of said antibody, and the TrkB receptor agonist can be used for treating a disease. Group XV is patentably distinct from groups XI-XII for the same reason.

Group XIV is unrelated to groups I-II, V-VII, X-XIII and XVI because the composition of group XIV is not used or otherwise involved in the process of groups I-II, V-VII, X-XIII and XVI.

Group XV is unrelated to groups I-II, V-X, XIII and XVI because the composition of group XV is not used or otherwise involved in the process of groups I-II, V-X, XIII and XVI.

Groups VIII-X, groups XI-XIII are distinct from each other because they are drawn to methods of using different compositions having different chemical structures, physical properties and biological functions, and requiring separate search: **TrkB receptor agonist or antagonist** vs. **GFRalpha/cRET receptor agonist or antagonist**. They are drawn to methods that differ at least in method steps, reagents and/or dosages used, schedules used, response variables, and criteria for success. They require separate search and the search would not be coextensive. Thus, they are patentably distinct from each other.

Groups I-II, V-VII, groups VIII-XIII and group XVI are drawn to different methods that differ in objectives, method steps, reagents and/or dosages used, schedules used, response variables, and criteria for success. They have different classifications and require separate search, and the search would not be coextensive. Thus, they are patentably distinct from each other.

Groups III-IV are unrelated to groups VIII-XIII and XVI because the compositions of groups III-IV are not used or otherwise involved in the process of groups VIII-XIII and XVI.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen, Ph.D.

SHIN-LIN CHEN
PRIMARY EXAMINER